# EXHIBIT 14

Department of Health and Human Services

# OFFICE OF INSPECTOR GENERAL

# MEDICAID PHARMACY - ACTUAL ACQUISITION COST OF GENERIC PRESCRIPTION DRUG PRODUCTS

2304849

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# SUMMARY

At the request of the Health Care Financing Administration (HCFA), the Office of Inspector General (OIG) conducted a nationwide review of pharmacy acquisition cost for generic drugs reimbursed under the Medicaid prescription drug program. Since most States reimburse pharmacies for Medicaid prescriptions using a formula which discounts the average wholesale price (AWP), the objective of our review was to develop a nationwide estimate of the discount below AWP at which pharmacies purchase generic drugs. Estimates for brand name drugs were also developed and those results were reported in a separate report.

To accomplish our objective, we selected a random sample of 11 States from a universe of 48 States and the District of Columbia. Arizona was excluded from the universe of States because the Medicaid drug program is a demonstration project using prepaid capitation financing and Tennessee was excluded because of a waiver received to implement a statewide managed care program for Medicaid. The sample States were California, Delaware, District of Columbia, Florida, Maryland, Missouri, Montana, Nebraska, New Jersey, North Carolina, and Virginia. We obtained pricing information from 314 pharmacies. Specifically, we obtained 9,075 invoice prices for generic drugs.

We estimated that, on average, actual acquisition cost of generic drugs was 42.5 percent below AWP. Unlike brand name drugs, where reimbursement is predominantly based on a discounted AWP, reimbursement of generic drugs can be limited by Federal upper limit amounts that are established by HCFA. Taking the upper limits into consideration, we calculated a savings of as much as $145.5 million in Calendar Years (CY) 1994 and 1995 for 200 generic drugs with the greatest amount of Medicaid reimbursement in each year, if reimbursement had been based on the findings of this report.

For the 11 States, we selected a sample of Medicaid pharmacy providers and obtained invoices of their drug purchases. The pharmacies were selected from each of five categories--rural-chain, rural-independent, urban-chain, urban-independent, and non-traditional pharmacies (nursing home pharmacies, hospital pharmacies, etc.). We excluded the non-traditional category from our overall estimates. We believed such pharmacies purchase drugs at substantially greater discounts than retail pharmacies, and including them would have inflated our percentages.

We compared each invoice drug price to AWP for that drug and calculated the percentage, if any, by which the invoice price was discounted below AWP. We then projected those differences to the universe of pharmacies in each category for each State and calculated an overall estimate for each State. Additionally, we projected the results from each State to estimate the nationwide difference between invoice price and AWP for each category.

We are recommending that HCFA work to ensure that States reimburse the ingredient portion of Medicaid drugs in a manner more consistent with the findings of this report. Additionally, we

are recommending that HCFA study any of the other factors (for example, dispensing fees) which they believe could significantly impact pharmacy reimbursement. We remain available to assist HCFA in implementing these recommendations.

The HCFA Administrator responded to our draft report in a memorandum dated July 7, 1997. The HCFA concurred with the findings and recommendations of this report. The HCFA hoped that this report would provide the necessary impetus for States to restructure their payment methodology for outpatient drugs. The full text of HCFA's comments is included in Appendix 3.

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# INTRODUCTION

At HCFA's request, the OIG, Office of Audit Services (OAS) conducted a nationwide review of pharmacy acquisition cost for drugs reimbursed under the Medicaid prescription drug program. The objective of our review was to develop a nationwide estimate of the difference between actual acquisition cost of drugs by the retail pharmacy and AWP for generic drugs.

## BACKGROUND

Medicaid regulations provide for the reimbursement of drugs using two methods. If a drug is a multiple source (generic) drug, then reimbursement is based on the lower of the pharmacist's usual and customary charge to the general public or a Federal upper limit amount plus a dispensing fee. The Federal upper limit amounts are established by HCFA. If a drug is a single source (brand name) drug, or a generic drug for which an upper limit amount has not been established, then the reimbursement is the lower of the pharmacist's usual and customary charge to the general public or the estimated acquisition costs (EAC) plus a reasonable dispensing fee. The State agencies are responsible for determining the EAC and the dispensing fee.

The EAC for most States is calculated by using AWP for a drug less a discount percentage. The AWP is the price assigned to the drug by its manufacturer and is listed in either the **Red Book**, **Medispan** or the **Blue Book**--publications universally used in the pharmaceutical industry. Prior to 1984, most States used 100 percent of AWP for reimbursement of acquisition cost. However, the OIG issued a report in 1984 which stated that, on average, pharmacies purchased drugs for 15.9 percent below AWP. In 1989, the OIG issued a follow-up report which concluded that pharmacies were purchasing drugs at discounts of 15.5 percent below AWP. Both the 1984 and 1989 reports combined brand name and generic drugs in calculating the percentage discounts and included a comparison of 3,469 and 4,723 purchases, respectively.

In 1989, HCFA issued a revision to the State Medicaid Manual which pointed out that a preponderance of evidence demonstrated that AWP overstated prices that pharmacies actually paid for drugs by as much as 10 to 20 percent. The Manual issuance further provided that, absent valid documentation to the contrary, it would not be acceptable for a State to make reimbursements using AWP without a significant discount.

In November 1990, the Omnibus Budget Reconciliation Act of 1990 was passed which placed a 4-year moratorium on changes to States' reimbursement policies. The moratorium expired on December 31, 1994 and HCFA requested that we, once again, determine the difference between AWP and actual pharmacy acquisition cost.

An article in the June 10, 1996 issue of **Barron's** entitled, "*Hooked on Drugs,*" focused additional attention on AWP and its relationship to actual acquisition cost. **Barron's** compared

about 300 dose forms of the top 20 Medicare drugs and concluded that the true cost was 10 to 20 percent below AWP for brand name drugs and 60 to 85 percent below AWP for generic drugs. **Barron's** also reported that industry insiders joke that AWP really means "Ain't What's Paid".

## SCOPE

Our review was performed in accordance with generally accepted government auditing standards. The objective of our review was to develop a nationwide estimate of the difference between the actual invoice prices of generic prescription drugs to Medicaid pharmacy providers and AWP. Our objective did not require that we identify or review any internal control systems.

Our review was limited to ingredient acquisition costs and did not address other areas such as: the effect of Medicaid business as a contribution to other store sales; the cost to provide professional services other than dispensing a prescription such as therapeutic interventions, patient education, and physician consultation; and the cost of dispensing which includes costs for computers, multipart labels, containers, technical staff, transaction fees, Medicaid specific administrative costs, and general overhead.

To accomplish our objective, we designed a multistage sampling procedure (a detailed description of our sample design is included as **Appendix 1** to this report). State Medicaid agencies were designated as the primary units and Medicaid pharmacy providers as the secondary units. We selected a random sample of 11 States from a universe of 49 States including the District of Columbia. Arizona was excluded from the universe of States because the Medicaid drug program is a demonstration project using prepaid capitation financing and Tennessee was excluded because of a waiver received to implement a managed care program for Medicaid. The States selected were California, Delaware, District of Columbia, Florida, Maryland, Missouri, Montana, Nebraska, New Jersey, North Carolina and Virginia.

We obtained a listing of all Medicaid pharmacy providers from each sample State. The State Agencies were responsible for classifying each pharmacy as a chain, independent or non-traditional. For purposes of this review, a chain was defined as four or more pharmacies with common ownership. We determined whether each pharmacy was rural or urban by comparing the county location for each pharmacy to a December 31, 1992 listing of the metropolitan areas and their components. We selected a stratified random sample of 60 pharmacies from each State with 12 pharmacies selected from each of 5 strata--urban-chain, rural-chain, urban-independent, rural-independent, and non-traditional (nursing home pharmacies, hospital pharmacies, home IV, etc.) If a stratum had a universe of less than 12, we selected 100 percent of the pharmacies in that stratum. We included the non-traditional category so as to be able to exclude those pharmacies from our estimates. We believed that such pharmacies are able to purchase drugs at substantially greater discounts than a retail pharmacy and would inflate our estimate.

We requested, from each pharmacy selected, the largest invoice from each different source of supply for a specified month in CY 1994. We identified the sources of supply as wholesalers, chain warehouse distribution centers, and direct manufacturer purchases. Each pharmacy was initially assigned a month from January through September in order to provide a cross section of this 9-month time period. However, we permitted some pharmacies to provide invoices from October, November or December as invoices were not available from the earlier period.

We reviewed every line item on the invoices supplied by the sample pharmacies to ensure that invoices contained the information necessary for our review. We eliminated over-the-counter items. Some invoices did not include National Drug Codes (NDC), which was needed to obtain AWP for the drug. We attempted to obtain NDCs in those instances. We used the **1994 Red Book,** a nationally recognized reference for drug product and pricing information, to obtain NDCs or identify over-the-counter items. One prominent wholesaler, whose invoices contained that wholesaler's item numbers rather than NDCs, provided us with a listing that converted their item numbers to NDCs. If we were unable to identify the NDC for a drug, we eliminated the line item.

We obtained a listing from HCFA that indicated whether a drug is a brand name or generic drug. We used that listing to identify the generic drugs on the invoices. If a drug was not on the HCFA listing, we used the **Red Book** to determine whether the drug was a generic drug. We also obtained from HCFA a listing of the top 200 generic drugs in terms of the amount reimbursed by Medicaid for CY 1994 and for CY 1995. The listing also included the total units reimbursed for those drugs.

The State of Missouri provided us with a pricing file for the purpose of obtaining AWP for each drug. We compared the invoice drug price to AWP for each drug and calculated the percentage, if any, by which the invoice price was discounted below AWP. If a drug from an invoice was not on the pricing file, we eliminated that drug.

We involved State agency officials in planning the methodology for this review. A meeting was held in Richmond, Virginia, with HCFA officials and Medicaid pharmacy representatives from the sample States to collaboratively design our approach. A second meeting was also held in Richmond, Virginia involving HCFA officials and pharmacy representatives from the sample States to present the results of our review and discuss how best to present these results to the States.

We used OAS statistical software to calculate all estimates as well as to generate all random numbers. We obtained the total number of pharmacies in the universe and State reimbursement information from the September 1994 issue of **Pharmaceutical Benefits Under State Medical Assistance Programs**. We did not independently verify any information obtained from third

party sources. Our review was conducted by the staff of the OAS Field Office in Little Rock, Arkansas with assistance from staff in our OAS Field Offices in Baton Rouge, Louisiana, Austin, Texas, and Oklahoma City, Oklahoma from September 1994 to September 1995.

## FINDINGS AND RECOMMENDATIONS

We estimated that pharmacies pay an average of 42.5 percent less than AWP for drugs sold to Medicaid beneficiaries. The estimate combined all pharmacy categories except non-traditional pharmacies and was based on the comparison of AWP for 9,075 invoice prices received from 314 pharmacies in the 11 State sample. The standard error for this estimate was .90 percent.

The estimates by individual categories for generic drugs are summarized in the following table:

| Category | Point Estimate | Standard Error | Sample Pharmacies | Prices Compared |
|---|---|---|---|---|
| Rural-Chain | 47.5 | 1.63 | 73 | 2,963 |
| Rural-Independent | 47.4 | .93 | 78 | 1,798 |
| Urban-Chain | 37.6 | 2.82 | 72 | 2,634 |
| Urban-Independent | 46.7 | 2.44 | 91 | 1,680 |
| Non-Traditional | 57.7 | 1.98 | 59 | 1,262 |
| Overall (Exc. Non-Trad.) | 42.5 | .90 | 314 | 9,075 |

While the estimate of the discount below AWP of invoice price for generic drugs is significant, this difference is mitigated by Federal upper limit amounts for generic drugs. Reimbursement for the ingredient cost, or EAC, of generic drugs is limited to the upper limit amounts established by HCFA. The upper limit amounts are based on 150 percent of AWP for the lowest priced generic equivalent. However, every generic drug does not have an upper limit established and in those cases, reimbursement of EAC is the same as reimbursement of EAC for brand name drugs. The EAC for brand name drugs is predominantly based on a discounted AWP, with 10 percent being the most common discount. Therefore, reimbursement of generic drugs which do not have upper limits is greatly in excess of the actual cost of the drug.

In order to assess the significance of the difference between what pharmacists pay for generic drugs and what Medicaid reimburses for those drugs, we calculated the difference for the 200 generic drugs with the most Medicaid reimbursement in CY 1994 and for the 200 with the most Medicaid reimbursement in CY 1995. For 187 drugs with upper limit amounts, we multiplied Medicaid utilization by the difference between the upper limit (what Medicaid pays for EAC) and

AWP discounted by 42.5 percent (pharmacy cost per our review). For 213 drugs without upper limits, we multiplied Medicaid utilization by AWP discounted by the difference between 42.5 percent and the most commonly used discount of 10 percent. We used the AWP for each drug that was in effect January 1, 1994 and January 1, 1995, respectively. We also used the upper limit amount that was in effect January 1, 1994 or January 1, 1995.

The difference between what Medicaid reimburses for ingredient cost and our estimate of what pharmacies actually pay was $145.5 million for the 2-year period. The majority, $132.7 million, of the difference was attributable to the 213 drugs without upper limits established. Reimbursement for 112 of the 187 drugs with upper limits was $37.3 million more than the estimated cost and reimbursement for the remaining 75 drugs was $24.5 million less than estimated cost. The following table details the results of our calculations:

| | 1994 | 1995 | 1994 & 1995 | Difference between Reimbursement and Acq. Cost * | Total Reimbursement by Medicaid |
|---|---|---|---|---|---|
| Drugs without upper limits | 116 | 97 | 213 | $132,656 | $414,408 |
| Drugs with upper limits greater than cost | 54 | 58 | 112 | $37,304 | $153,725 |
| Drugs with upper limits less than cost | 30 | 45 | 75 | $(24,495) | $90,977 |
| Totals | 200 | 200 | 400 | $145,465 | $659,110 |

* - Amounts in thousands

## CONCLUSIONS AND RECOMMENDATIONS

Based on our review, we have determined that there is a significant difference between pharmacy acquisition cost and AWP. We have also calculated that changing reimbursement policy consistent with the findings of our report could have resulted in savings of as much as $145.5 million in CY 1994 and CY 1995 for the 200 most reimbursed drugs in each year. We recognize that these calculations do not incorporate all the complexities of pharmacy reimbursement and that acquisition cost is just one factor in pharmacy reimbursement policy. We believe that any change to that policy should also consider the other factors discussed in the Scope section of our report. However, we also believe that the results of this report are significant enough to warrant a review of pharmacy reimbursement policy.

Therefore, we recommend that HCFA work to ensure that States reimburse the ingredient portion of Medicaid drugs in a manner more consistent with the findings of this report. Additionally, we recommend that HCFA study any of the other factors which they believe could significantly impact pharmacy reimbursement.

## HCFA'S COMMENTS

The HCFA Administrator responded to our draft report in a memorandum dated July 7, 1997. The HCFA concurred with the findings and recommendations of this report. The HCFA hoped that this report would provide the necessary impetus for States to restructure their payment methodology for outpatient drugs. The full text of HCFA's comments is included in Appendix 3.

# APPENDICES

# SAMPLE DESCRIPTION

*Sample Objectives:*

Develop a nationwide estimate of the extent of the discount below average wholesale prices (AWP) of actual invoice prices to Medicaid pharmacies for generic drugs.

*Population:*

The primary sampling population was all States providing coverage of prescription drugs as an optional service under Section 1905 (a) (12) of the Social Security Act. Section 1903 (a) of the Act provides for Federal financial participation (FFP) in State expenditures for prescription drugs.

*Sampling Frame:*

The primary sampling frame was a listing of all States participating in the Medicaid prescription drug program except for Arizona and Tennessee. Arizona was excluded because the Medicaid drug program is a demonstration project using prepaid capitation financing and Tennessee was excluded because of a waiver received to implement a managed care program for Medicaid.

*Sample Design:*

A multistage sample was designed with States as the primary sample units and Medicaid pharmacy providers within those States as the secondary sample units. A simple random sample of States was selected for the primary sample and a stratified random sample of pharmacies was selected for the secondary sample. A sample of 12 pharmacies was selected from each of 5 strata. The 5 strata of pharmacies were rural-chain, rural-independent, urban-chain, urban-independent, and non-traditional (nursing home pharmacies, hospital pharmacies, home IV, etc.). Each pharmacy was assigned a month from 1994 for which to provide invoices. All pharmacies were initially assigned a month from January through September in a method designed to provide a cross section of the 9-month period. However, some pharmacies were permitted to submit invoices from October, November or December as invoices were not available for the month originally

assigned. The largest invoice from each of four different sources of supply was requested. The sources of supply were identified as wholesalers, chain warehouse distribution centers, and direct manufacturer purchases. All invoice prices were compared to AWP.

*Sample Size*:

Eleven States were selected for review from our primary sampling frame. Twelve pharmacies were selected from each stratum of our secondary sample frame. A maximum of 60 pharmacies was selected from each State. Some States did not have 12 pharmacies in all strata or have every strata.

*Source of Random Numbers*:

OAS statistical sampling software was used to generate the random numbers.

*Characteristics to be Measured*:

From our review of the pharmacy invoices we calculated the percentage of the discount below AWP of actual invoice prices for all drugs on the invoices submitted.

*Treatment of Missing Sample Items*:

No spare was substituted for a pharmacy that did not respond to our request or did not provide usable information. If a pharmacy stratum had 12 or fewer pharmacies, we reviewed all of the pharmacies in that stratum. If a pharmacy did not send an invoice for a particular type of supplier, we assumed that the pharmacy did not purchase drugs from that type of supplier during the month assigned to the pharmacy.

*Estimation Methodology*:

We used OAS statistical software for multistage variable sampling to project the percentage difference between actual invoice prices and AWP for each stratum, as well as an overall percent difference.

*Other Evidence*:

We obtained AWP from First DataBank.

**APPENDIX 2**

# NATIONWIDE SAMPLE RESULTS
# GENERIC NAME DRUGS

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| RURAL-CHAIN | 1,095 | 73 | 2,963 | 47.51 | 1.63 | 44.82 | 50.20 |
| RURAL-INDEPENDENT | 1,499 | 78 | 1,798 | 47.38 | 0.93 | 45.85 | 48.92 |
| URBAN-CHAIN | 8,194 | 72 | 2,634 | 37.61 | 2.82 | 32.97 | 42.26 |
| URBAN-INDEPENDENT | 6,242 | 91 | 1,680 | 46.72 | 2.44 | 42.70 | 50.73 |
| NON-TRADITIONAL | 2,026 | 59 | 1,262 | 57.70 | 1.98 | 54.43 | 60.96 |
| OVERALL (EXCL. NON-TRAD) | 17,030 | 314 | 9,075 | 42.45 | 0.90 | 40.97 | 43.93 |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

The Administrator
Washington, D.C. 20201

JUL 7 1997

DATE:

TO: June Gibbs Brown
Inspector General

FROM: Bruce C. Vladeck
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Medicaid Pharmacy--Actual Acquisition Cost of Generic Prescription Drug Products," (A-06-97-00011)

We reviewed the above-referenced report concerning the pharmacy acquisition cost for generic drugs reimbursed under the Medicaid prescription drug program.

Our detailed comments are attached for your consideration. Thank you for the opportunity to review and comment on this report.

Attachment

Health Care Financing Administration (HCFA) Comments on
Office of Inspector General (OIG) Draft Report Entitled:
"Medicaid Pharmacy--Actual Acquisition Cost of Generic Prescription Drug Products,"
(A-06-97-00011)

OIG Recommendation

HCFA should work to ensure that states reimburse the ingredient portion of Medicaid drugs in a manner more consistent with the findings of this report. Additionally, HCFA should study any of the other factors it believes could significantly impact pharmacy reimbursement.

HCFA Response

We concur. The findings shown in the report confirm the belief shared by many states that the pharmacy's actual generic drug acquisition costs are much less than the prices paid by many states to the pharmacies. An increasing number of state outpatient drug programs are changing the basis for reimbursing ingredient costs from the average wholesale price to the lower of the wholesaler acquisition cost, the usual and customary charge, or the estimated acquisition cost, in order to be closer to the actual price paid by the pharmacy to acquire the drug. This report provides a monetary incentive for states to reassess their drug reimbursement methodology as they look for ways to stretch their operating budgets.

The report also recommends that HCFA study other factors that affect drug costs such as dispensing fees. Regional office personnel who function as drug rebate coordinators polled the states in their regions in both 1995 and 1996 to ascertain whether states are considering lowering the dispensing fee. Their findings indicate that states are beginning to consider reducing their dispensing fees only when the need for additional savings becomes critical. However, based on the number of states that are changing to capitated reimbursement arrangements, we believe the lowering of state dispensing fees is becoming less important.

We believe the findings in this report are significant and warrant the attention of all state Medicaid agencies. We intend to share this report with all state Medicaid agencies and hope this report will provide the necessary impetus for states to restructure their payment methodology for outpatient drugs.